

**REMARKS/ARGUMENTS****Restricted Claims**

The restriction of claims 1, 2 and 5 is respectfully traversed. There is only one general inventive concept for all of these claims, which is the use of ectoine, hydroxyl ectoine, or a pharmaceutical acceptable salt thereof for the treatment of certain diseases. The pending claims relate to a method of treatment, a method of production, and an inhalation device, all comprising said substances. Moreover, original claims 1, 2 and 5, which were "use" claims and were not restricted by the Examiner, were merely recast into "method" claims in keeping with U.S. practice. Since the claims involve only one general inventive concept, and no restriction was initially raised to the claims, claims 1, 2 and 5 should not be restricted now. Thus, Applicants request that claims 1, 2 and 5 be considered in the current application.

**Declaration**

A declaration identifying the application by application number is submitted herewith.

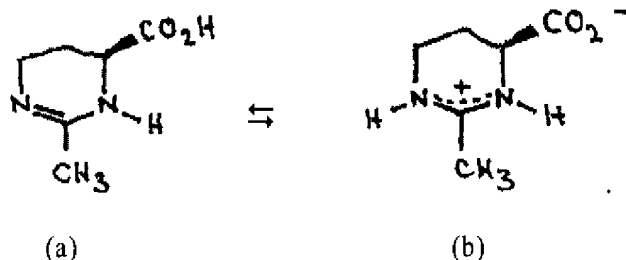
**Specification**

The specification is amended to remove references to URLs.

**Claim Rejections**

The rejection of claims 6-8 as obvious over U.S. Patent 6,716,819 to Welsh et al. ('819) in view of US 2003/0054021 ('021) and US 2003/0021817 ('817) is respectfully traversed. The '819 patent teaches away from using a zwitterion such as ectoine. Moreover, the number of possible osmolytes that could be used in combination with the '819 patent is too large, and their properties too uncertain, to be the basis of an "obvious to try" rationale. Thus, claims 6-8 are not obvious.

Claims 6-8 recite an osmolyte selected from ectoine, hydroxyectoine or a pharmacologically compatible salt thereof. Ectoine is a cyclic amino acid having the following structure:



As with other amino acids, ectoine is a zwitterion and is therefore ionic under physiological conditions (see zwitterionic structure in (b) above).

According to the Office Action, it would be obvious to substitute the xylitol taught in the '819 patent with the ectoine taught in the '021 and '817 references. However, the '819 patent teaches away from using an ionic osmolyte such as ectoine. In particular, the '819 patent indicates throughout that the osmolyte must be "non-ionic" (for example, see col. 5, ln. 65-67; col. 6, ln. 6-11; col. 7, ln. 27-29; col. 9, ln. 56-58). Furthermore, as a consideration for use as an osmolyte, the '819 patent indicates that "an osmolyte that is non-ionic would be required" (col. 5, ln. 14-16). Moreover, the purpose of the '819 patent is to lower the ionic strength in body fluids (col. 5, ln. 59-60) since it is lower ionic strength that restores antimicrobial activity (col. 5, ln. 14-16; col. 7, ln. 17-30). The use of an ionic osmolyte is therefore prohibited since an ionic osmolyte would increase, rather than decrease, the ionic strength.

In sum, the '819 patent teaches away from using an ionic osmolyte such as ectoine. Furthermore, nothing in the '021 or '817 references overcomes this teaching away. Because the use of ectoine in combination with the '819 patent is excluded by the prior art, claims 6-8 are not obvious.

Moreover, references cannot be combined when the references teach away from their combination. MPEP 2145(X)(D). In the present case, the '819 patent teaches away from the use of ectoine, and thus teaches away from its combination with the '021 and '817 references. Because the combination of cited references is improper, a *prima facie* case of obvious cannot be made for claims 6-8. As such, claims 6-8 are not obvious.

Further, ectoines are only a small fraction of the group of osmolytes. Indeed, many thousands of compounds have osmolytic properties. In addition, not all osmolytes have the same properties – for example, as shown in Fig. 5a to 5c of the '819 patent, xylitol cannot support bacterial growth whereas bacteria can grow on other osmolytes such as succinate, mannitol and sucrose. Because the number of osmolytes is large, and osmolytic properties are different from one osmolyte to another, there is no finite number of predictable solutions that can be applied to the preparation of an inhalation device. Thus, claims 6-8 cannot be obvious under an "obvious to try" rationale.

The '819 patent teaches away from the use of ectoine, the combination of cited references is improper, and the number of possible solutions is too large and unpredictable. For each of these reasons, claims 6-8 are not obvious.

In view of the foregoing amendments and remarks, Applicants submit that the present application is in condition for allowance. A Notice of Allowance is therefore respectfully requested.

A Petition and fee for a three-month extension of time is being submitted herewith.

This Amendment is submitted as part of a Request for Continued Examination.

Application No.: 10/563,587

Docket No.: 7290-106

No additional fees are believed due. However, the Commissioner is hereby authorized during prosecution of this application and any related appeal, to charge any fees that may be required (except for patent issue fees required under 37 CFR §1.18) or to credit any overpayment of fees to Deposit Account No. 50-3881, under Order No. 7290-106.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Miles Yamanaka", with a long horizontal stroke extending to the right.

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Enclosure: Declaration for Patent Application